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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,358

09/11/2003

Michael Croft

051501-0305443

6765

7590

05/26/2006

Pillsbury Winthrop LLP
Intellectual Property Group
Suite 200
11682 El Camino Real
San Diego, CA 92130-2092

EXAMINER

OUSPENSKI, ILIA I

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,358

Applicant(s)

CROFT ET AL.

Examiner

ILIA OUSPENSKI

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 10, 12 - 14, 21 - 22, and 40 - 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 9, 11, 15 - 20, 23 - 39, and 69 - 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment/remarks, filed 03/27/2006, are acknowledged.

Claims 1 – 76 are pending.

Claims 10, 12 – 14, 21 – 22, and 40 – 68 have been withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions (see Office Action mailed 09/26/2005).

Claims 71 and 72 have been amended.

Claims 1 – 9, 11, 15 – 20, 23 – 39, and 69 – 76 are under consideration in the instant application, as they read on methods comprising administering an antibody to OX40L.

2. This Office Action will be in response to applicant's amendment and arguments, filed 03/27/2006.

The rejections of record can be found in the previous Office Action, mailed 09/26/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

3. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

4. The oath or declaration is defective because: signature of co-inventor Sharam Salek-Ardakani is not dated.

Applicant's arguments have been fully considered but have not been found convincing, for the following reason:

"U.S. Patent and Trademark Office personnel are authorized to accept a statutory declaration under 28 U.S.C. 1746 filed in the U.S. Patent and Trademark Office in lieu of an "oath" or declaration under 35 U.S.C. 25 and 37 CFR 1.68, provided that the statutory declaration otherwise complies with the requirements of law.

Section 1746 of Title 28 of the United States Code provides:

Whenever, under any law of the United States or under any rule, regulation, order, or requirement made pursuant to law, any matter is required to be supported, evidenced, established, or proved by sworn declaration, verification, certificate, statement, oath or affidavit, in writing of the person making the same (other than a deposition, or an oath of office, or an oath required to be taken before a specified official other than notary public), such matter may, with like force and effect, be supported, evidenced, established, or proved by the unsworn declaration, certificate, verification, or statement, in writing of such person which is subscribed by him, as true under penalty of perjury, and **dated** [...]" (emphasis added). See MPEP §602, section II: "Statutory Declarations."

A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required.

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5. Claim 1 – 9, 15 – 20, 23 – 39, and 69 – 76 stand rejected under **35 U.S.C. 102(e)** as being anticipated by Arndt et al. (US Pat. Pub. No. 2004/0009174; see entire document).

The Declaration by Drs. Michael Croft and Shahram Salek-Ardakani, filed on 03/27/2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the reference of Arndt et al., for the following reasons:

The Declaration is not sufficient in scope of disclosure, relative to the scope of the instant claims and the scope of teachings in the prior art.

The instant claims encompass in their breadth methods of reducing or inhibiting a recall immune response by administering an agent that reduces or inhibits OX40 or OX40L signaling, expression, or activity.

The prior art reference of Arndt et al. broadly teaches methods of treating or preventing an inflammatory disease by administering an agent that inhibits interaction between OX40 and OX40L, such as a fusion protein comprising OX40 or an antibody to OX40 or to OX40L; or an agent inhibiting expression of OX40L, such as a DNAzyme, ribozyme, antisense RNA, dominant negative polypeptides, genetic suppression elements, or intracellular antibodies (see entire document, in particular, e.g. paragraphs 0008 – 0036; more specifically 008, and 0032 – 0034).

However, the Declaration is limited in scope to evidence of conception and reduction to practice of a method of using anti-OX40L antibodies to treat asthmatic lung inflammation in a mouse model. As such, the Declaration is insufficient in scope to overcome the teachings of the prior art reference of Arndt et al. See MPEP §§715.02 and 715.03.

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Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

6. Claims 1, 8, and 11 stand rejected under **35 U.S.C. 103(a)** as being unpatentable over Arndt et al. (US Pat. Pub. No. 2004/0009174; see entire document) in view of Owens et al. (Journal of Immunological Methods, 1994, 168: 149 - 165; see entire document).

Applicant relies on the Declaration by Drs. Michael Croft and Shahram Salek-Ardakani, filed on 03/27/2006 under 37 CFR 1.131, to argue that the reference of Arndt et al. is not available as prior art against the instant claims.

Applicant's arguments have been addressed in section 5, *supra*, and have not been found sufficiently persuasive. Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

7. Conclusion: no claim is allowed.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

May 22, 2006

Phillip Gambel
PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
TZ 1600
5/24/06